Cogent Biosciences Announces FDA Acceptance of New Drug Application (NDA) for Bezuclastinib in Patients with Advanced Systemic Mastocytosis (AdvSM)

September 15, 2026

NDA supported by positive results from the APEX pivotal trial demonstrating clinically meaningful responses and evidence of disease modification in patients with AdvSM

PDUFA target action date set for June 29, 2027

WALTHAM, Mass. and BOULDER, Colo., Sept. 15, 2026 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for bezuclastinib in patients with Advanced Systemic Mastocytosis (AdvSM) and assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 29, 2027. In addition, the FDA communicated that at this time, there is no plan to hold an advisory committee, nor have they identified any potential review issues.

"With the FDA's acceptance of our NDA in Advanced Systemic Mastocytosis, we have reached another important regulatory milestone for bezuclastinib and are one step closer to potentially bringing this therapy to patients with AdvSM," said Andrew Robbins, Cogent's President and Chief Executive Officer. "Together with the NDAs currently under review for NonAdvSM and GIST patients, this milestone further reinforces the potential of bezuclastinib across multiple patient populations with KIT-driven diseases. With an excellent commercial and medical team in place, we are excited and ready for the potential launches later this year."

The NDA acceptance is supported by data from the APEX pivotal trial, which was most recently presented at the 2026 European Hematology Association (EHA) Congress, in which bezuclastinib demonstrated clinically meaningful responses and durable clinical activity in patients with AdvSM. As of the March 31, 2026 data cutoff, the primary endpoint of response per mIWG-MRT-ECNM criteria demonstrated a 65% overall response rate, including 57% of patients achieving CR, CRh or PR as best response. Response by pure pathological response (PPR) criteria was 81%. Bezuclastinib also demonstrated durable clinical activity, with a 12-month progression-free survival rate of 79% and 12-month overall survival rate of 87%, with median PFS and OS not yet mature.

Cogent continues to advance bezuclastinib toward potential approvals and commercialization across its three indications. The Company's NDA for NonAdvanced Systemic Mastocytosis is under FDA review, with a PDUFA target action date of December 30, 2026, and the NDA for GIST is also under FDA review, with a PDUFA target action date of November 30, 2026. Together, these regulatory milestones represent significant progress toward bringing bezuclastinib to patients across a broad spectrum of KIT-driven diseases.

Bezuclastinib - Expanded Access Program
Working with the FDA, Cogent has established active Expanded Access Programs (EAPs) for U.S. patients with SM or GIST who meet disease-specific criteria and could benefit from treatment with bezuclastinib or the combination of bezuclastinib and sunitinib. For more information please visit: **https://www.cogentbio.com/bezuclastinib-program-development/#our-expanded-access-policy**.

Inducement Grants Under Nasdaq Listing Rule 5635(c)(4)
Cogent also announced today that, on September 10, 2026, the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, approved the grants of "inducement" equity awards to nine new employees under the company's 2020 Inducement Plan with grant dates of September 10, 2026 and September 14, 2026. The awards were approved in accordance with Listing Rule 5635(c)(4) of the corporate governance rules of the Nasdaq Stock Market. The employees received, in the aggregate, (i) nonqualified options to purchase 39,300 shares of Cogent common stock and (ii) 33,600 restricted stock units (RSUs). Each option has a 10-year term, an exercise price equal to the closing price of Cogent's common stock on the grant date, and a 4-year vesting schedule with 25% vesting on the 1-year anniversary of the grant date and the remainder vesting in equal monthly installments over the subsequent 36 months, provided such employee remains employed through each such vesting date. The RSUs vest annually in equal installments over 4 years from the grant date, provided such employee remains employed through each such vesting date.

About Cogent Biosciences, Inc.
Cogent Biosciences is a biotechnology company focused on developing precision therapies for genetically defined diseases. The

most advanced clinical program, bezuclastinib, is a selective tyrosine kinase inhibitor that is designed to potently inhibit the KIT D816V mutation as well as other mutations in KIT exon 17. KIT D816V is responsible for driving systemic mastocytosis, a serious disease caused by unchecked proliferation of mast cells. Exon 17 mutations are also found in patients with advanced gastrointestinal stromal tumors (GIST), a type of cancer with strong dependence on oncogenic KIT signaling. In addition, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases targeting mutations in ErbB2, PI3Kα, KRAS and JAK2. Cogent Biosciences is based in Waltham, MA and Boulder, CO. Visit our website for more information at **www.cogentbio.com**. Follow Cogent Biosciences on social media: **X** and **LinkedIn**. Information that may be important to investors will be routinely posted on our website and **X**.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding: the potential for regulatory approval and commercialization of bezuclastinib across three indications: patients with GIST, NonAdvSM and AdvSM; bezuclastinib's potential across multiple KIT-driven diseases and the potential commercial launches of bezuclastinib later this year. The use of words such as, but not limited to, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," or "would" and similar words expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results, the rate of enrollment in our clinical trials and other future conditions. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. We may not actually achieve the forecasts or milestones disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption "Risk Factors" in Cogent's most recent Quarterly Report on Form 10-Q filed with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither we, nor our affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date hereof.

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